Eur J Vasc Endovasc Surg (2009) **37**, 239–245

Outcome of Endovenous Laser Therapy for Saphenous Reflux and Varicose Veins: Medium-Term Results Assessed by Ultrasound Surveillance

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Submitted 10 October 2007; accepted 2 September 2008
Available online 6 November 2008

KEYWORDS
Endovenous;
Laser;
Sclerotherapy;
Ultrasound;
Veins;
Varicose;
Saphenous

Abstract *Objective:* To assess the efficacy of endovenous laser therapy (EVLT) for treating saphenous reflux associated with varicose veins.
Design: Out-patient treatment by EVLT with an 810 nm laser wavelength with results assessed by ultrasound surveillance.
Patients: 361 patients who received EVLT for 509 incompetent saphenous veins over a five-year period.
Methods: EVLT was used for proximal saphenous veins and ultrasound-guided sclerotherapy (UGS) for distal saphenous veins and tributaries. Control of reflux and occlusion or obliteration of the saphenous veins was assessed by serial ultrasound studies. Univariate Kaplan–Meier life table analysis showed cumulative primary and secondary success rates, and multivariate Cox regression analysis assessed covariates that could be associated with increased risk of ultrasound failure.
Results: Life table analysis showed primary success at four years in 76% (95% CI 56–87%) and secondary success at four years after further treatment of recurrence by UGS in 97% (95% CI 93–99%). Cox regression analysis showed a non-significant trend towards worse primary success in male patients and worse results for older patients and limbs with clinical CEAP categories C4–6. Cox regression showed significantly worse secondary success for limbs with clinical CEAP C4–6.
Conclusions: EVLT effectively controls saphenous reflux particularly with ultrasound surveillance to detect early recurrence that can be treated by UGS. Modifications in technique may be required to improve the late primary success rate.

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1078-5884/$34
doi:10.1016/j.ejvs.2008.09.009

Introduction

Treatment of saphenous vein reflux by surgery leads to disruption of activities, appreciable trauma, scarring and high late recurrence rates.[1] Non-surgical endovenous techniques are becoming increasingly popular with practitioners and patients. Endovenous laser therapy (EVLT) provides a percutaneous method to destroy larger diameter saphenous veins. EVLT is an out-patient procedure performed under local anaesthesia and is associated with minimal post-treatment morbidity and no surgical trauma.[2–5] This article analyses medium-term results after EVLT for 509 saphenous veins in 361 patients followed by ultrasound surveillance.

Patients and Methods

The procedure was introduced in January 2002 with follow-up for analysis continued until June 2007. All patients were treated by the one surgeon (KM). Ethics committee approval had been obtained for endovenous treatment of varicose veins. EVLT was offered to patients where preliminary ultrasound scanning showed great or small saphenous reflux with a straight section of vein of diameter greater than approximately 5 mm. Duplex scanning performed by specialist vascular sonographers linked to the surgical unit was used to detect superficial, deep and perforator reflux, mark the site and extent of disease, and measure the length and diameters of refluxing saphenous veins prior to the procedure.

Technique for EVLT

EVLT was performed using the Diomed 810 nm diode system (Diomed Inc., Andover, MA, USA) under tumescent anaesthesia without sedation. Ultrasound imaging was used with a 12–5 MHz linear array probe. The distal end of vein and saphenofemoral or sapheno-popliteal junction were marked. The limb was draped and the operator wore a surgical gown and gloves. The skin at the puncture site was infiltrated with 1% plain lidocaine and a 19 g angiogram inserted under longitudinal ultrasound imaging. A 0.035 in. safety-J guidewire was passed along the vein to the saphenous junction, and a 45 cm long 5F sheath is passed over the wire to the junction. Occasionally the vein had to be treated in two sections if the guidewire could not be passed the full length of the vein.

Ultrasound was used to guide injection of 10–15 ml aliquots of 0.2% lidocaine with adrenaline solution through a 25 gauge needle into the saphenous fascial compartment in which the vein lies along the entire length to be treated. A laser fibre was passed along the sheath, markers on the fibre allowing 2 cm of it to extend beyond the sheath. The tip was placed 2 cm below the saphenous junction confirmed by transillumination using the laser aiming beam. The fibre tip was placed above major thigh tributaries of the GSV. When treating the small saphenous vein the fibre was passed into the thigh extension of the SSV where this was possible.

The treatment power used in this series was 14 watts continuous power. The mean rate of withdrawal of the probe ranged from 1.3 to 8.8 mm/sec (median 3.1 mm/sec) – the faster rates were used early in the study. The mean power used ranged from 16 to 128 joules/cm (median 44 joules/cm).

Once the saphenous trunk had been treated the compression was applied with both bandages and a class 2 stocking. Immediate walking was encouraged. Compression with the stocking and bandages was maintained for 48 h and the stocking alone was then worn during the day for a further 7–10 days. Pain was readily controlled by oral analgesics and most patients were able to resume normal activities by the next day.

Further treatment by UGS for residual varices and saphenous trunk was required after 80% of procedures and usually performed 1–3 weeks after EVLT. Incompetent saphenous were treated in 70% of cases and the distal saphenous vein in 10%. UGS is performed with a 1.5% solution of sodium tetradecyl sulphate foamed with air or carbon dioxide/oxygen in a ratio of two parts fluid to three parts gas using a sufficient volume to fill the veins (median 5 ml). No surgical treatment was required in any limb.

Ultrasound surveillance

It was considered essential to repeat ultrasound at 3–5 days after the procedure to confirm that the treated vein had been occluded, to detect residual veins to be treated, and to exclude deep vein occlusion. The scan is repeated at 6 weeks, 6 monthly for 2 years then annually, looking for occlusion or obliteration, or for recanalisation of the vein.

Statistical analysis

Follow-up with serial ultrasound scans at the above intervals was used for survival analysis. Success was defined as continuing occlusion or obliteration without reflux in any segment of the treated vein determined by duplex ultrasonography. Primary failure was defined as failure to occlude the lumen or recanalisation with reflux in a part or all of the treated saphenous vein, whether or not this was associated with clinical persistence or recurrence of varicose veins. Secondary failure was defined as failure to occlude the lumen or recanalisation and reflux after primary failure, either because of a decision for no further treatment or if further treatment by UGS was unsuccessful.

Data were progressively censored as patients were seen at the most recent visit, were lost to follow up or died. Statistical analysis was performed using Stata V9.2 software. Univariable Kaplan–Meier survival-curve analysis was used to calculate primary and secondary ultrasound success rates. The time to failure was the difference between the date of EVLT and date that recurrent reflux was demonstrated at follow-up. All patients presented for this first post-procedure scan and if failure was noted at this scan then this date was used for failure although it is probable that the procedure had failed from the time it was performed. If a patient shown to have recurrence had missed a prior scheduled visit then recurrence was dated back to the time of that missed visit.

Multivariable Cox proportional hazard regression analysis was used to correlate success or failure independently with various covariates relating to the patients, limbs,

treated veins and technique. These were the age, sex and side, clinical CEAP category (C2—3 vs C4—6), vein treated (great or small saphenous), primary disease without previous treatment or recurrence after previous surgery, time for the date of procedure from the date for commencement of the surgeon's experience (days), length of vein treated (cm), representative diameter of vein (mm), rate of withdrawal of the laser probe (mm/sec), and power used (joule per cm).

To avoid linearity assumptions, we categorized continuous covariates. We selected categories based on quartiles of the variable's distribution, independent of its association with the outcome variable. We used a likelihood-ratio χ^2 test to assess the contribution of each predictor variable in a final model. The unit of analysis for Cox proportional hazard regression was the vein. We used the Huber/White sandwich estimator of variance to accommodate clustering of veins within the same patient. Each vein inherited the higher-level characteristics of its 'parent' limb and patient within the regression model.

Results

Patients and veins treated

EVLT was offered to patients where preliminary ultrasound scanning showed great or small saphenous reflux with a straight section of vein of diameter greater than approximately 5 mm. 509 saphenous veins were treated in 494 limbs of 361 patients. No patient has been excluded from the follow-up. There were 232 women (64%) and 129 men with an age range from 24 to 76 years (median 52 years). Both the great and small saphenous veins of the same limb were treated at the one procedure in 14 limbs of 12 patients. The great, small and anterior accessory saphenous veins of the same limb were treated at the one procedure in one patient. A saphenous vein from each limb was treated in 133 patients, initially as separate procedures but then always at the one session.

The CEAP classification showed that there were 449 limbs with uncomplicated varicose veins (C2—3—91%) and 45 limbs with complications (C4—6) due to lipodermatosclerosis ($n - 34$), healed past venous ulceration ($n - 5$) or active ulceration ($n - 6$). Primary disease (Pp) was present in all limbs and none had features of the post-thrombotic syndrome. There was persistent or recurrent reflux after past saphenous surgery by other surgeons in 48 limbs, 39 for great saphenous and 9 for small saphenous disease.

Results will be analysed for the great and anterior accessory veins grouped together and for the small saphenous veins and thigh extensions together. Treatment was for reflux in 405 great saphenous veins, 8 anterior accessory saphenous veins, and 96 small saphenous veins including the thigh extensions if diseased. The diameters ranged from 4 to 17 mm (median 7 mm) for great and anterior accessory saphenous and 4 to 10 mm (median 7 mm) for small saphenous veins (Fig. 1). The lengths of veins treated ranged from 10 to 48 cm (median 30 cm) for great and anterior accessory saphenous and 6 to 38 cm (median 18 cm) for small saphenous veins (Fig. 2).

Initial technical failure occurred in 5 of 509 procedures. In one limb treated for small saphenous reflux, the guidewire and laser probe passed outside the vein without this being recognized until after the procedure. In four other limbs treated for great saphenous reflux, it was considered that a large vein had not been adequately compressed onto the laser probe to achieve occlusion. There were 24 further limbs where recanalisation was detected on surveillance, usually to a minor degree when compared to the initial reflux. Recurrence followed EVLT for the great saphenous vein in 19 limbs, all from the saphenofemoral junction into the saphenous vein in 14 and a large thigh tributary in 5. Recurrence after EVLT for the small saphenous vein occurred in 5 limbs, all from the sapheno-popliteal junction into the small saphenous vein. Most recurrences occurred within the first 18 months but three late great saphenous recurrences were detected more than three years after treatment (Fig. 3).

This resulted in a primary ultrasound success rate at four years by life table analysis of 75.7% (95% CI 56.3—87.4%) (Fig. 4). All but 5 of these limbs were treated by UGS to obliterate the recurrent vein at intervals from 7 to 570 days after EVLT, and this has been successful to date in all limbs resulting in a secondary ultrasound success rate at four years by life table analysis of 97.2% (95% CI 93.2—98.9%) (Fig. 5).

Cox regression analysis for primary success showed that the only significant covariate relating to failure was gender

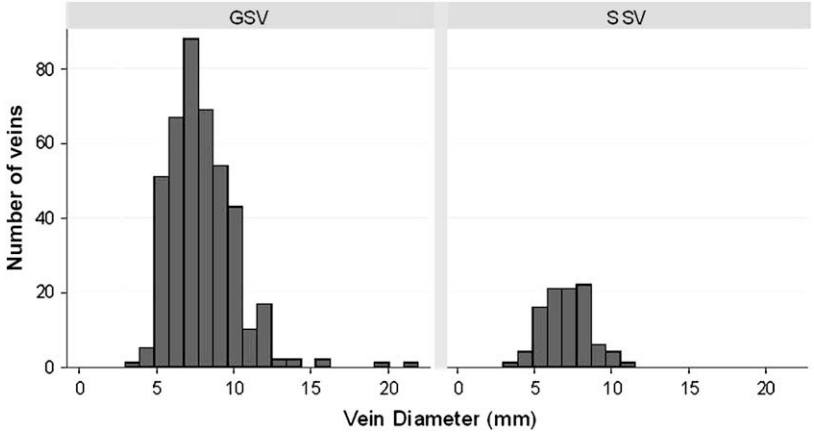

Figure 1 Histogram for distribution of diameters of great and small saphenous veins.

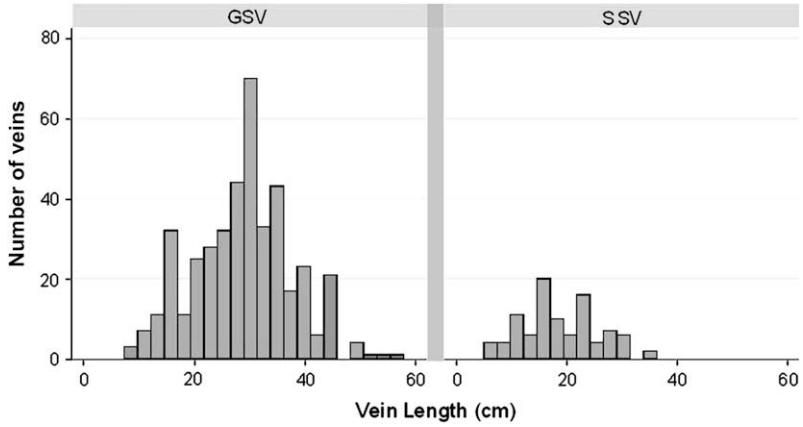

Figure 2 Histogram for distribution of lengths of great and small saphenous veins.

with better results in women (hazard ratio (HR) 0.44; 95% CI 0.20—1.00) (Fig. 6). There was a trend to worsen results in older patients aged greater than 60 (HR 1.51; 95% CI 0.53—4.31) and limbs with CEAP clinical C4—6 (HR 2.25; 95% CI 0.91—5.59) (Fig. 7) but these do not reach significance. Cox regression analysis for secondary success showed that the only significant covariate relating to failure was clinical CEAP C 4—6 (HR 12.24; 95% CI 2.02—74.07) (Fig. 8). Results are shown in Table 1. There was no significant influence on primary success according to the side, vein treated, primary disease without previous treatment or recurrence after surgery, the surgeon's experience, length of vein, representative diameter, rate of probe withdrawal or laser power.

Complications

One patient with very severe right heart failure and high venous pressures causing intermittent bleeding from varices developed severe painful inflammatory swelling along the treated great saphenous vein, and this was the only patient who subsequently died at 18 months from cardiac disease, unrelated to EVLT. Otherwise, all patients had temporary mild-to-moderate pain that was controlled by oral analgesics with no more than moderate bruising along the site.

Thromboembolic events occurred in 11 patients (3.0%). After EVLT for the great saphenous vein, there were two procedures where thrombus extended into the common femoral vein and two with thrombus in the popliteal vein at the first scan after EVLT. One patient developed symptomatic pulmonary embolism confirmed by CT scanning at three days with no deep vein thrombosis identified and no long-term sequelae. In addition, there were four limbs with tibial vein occlusions all occurring after UGS performed 1—4 weeks after EVLT. After EVLT for the small saphenous vein, one procedure was complicated by thrombus extension into the popliteal vein and one with non-occlusive thrombus in the femoral vein at the first scan, but there were no tibial vein occlusions. All deep vein occlusions were asymptomatic and detected only by ultrasound. Above-knee thromboses did not occlude the vein and completely resolved within one to two weeks. Tibial vein occlusions did not extend but also did not recanalise.

One patient has a partial sural nerve palsy at 18 months after small saphenous EVLT but there were no other nerve injuries or thermal damage. No other significant complications were encountered.

Discussion

EVLT is equally suited to young patients requiring the best cosmetic outcome and elderly patients with complications

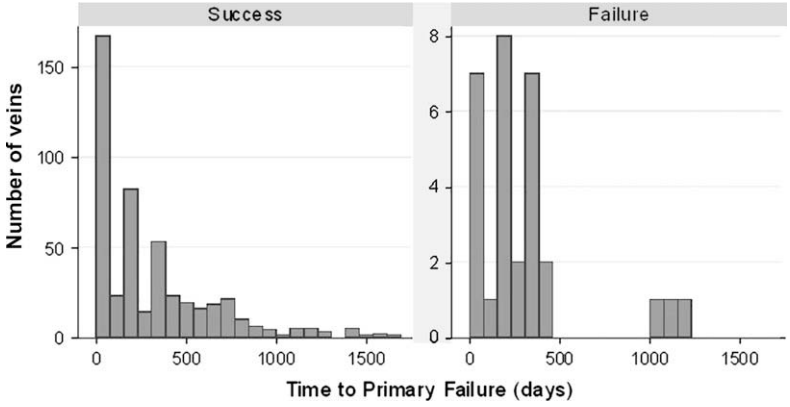

Figure 3 Histogram for times of primary success and failure for all veins.

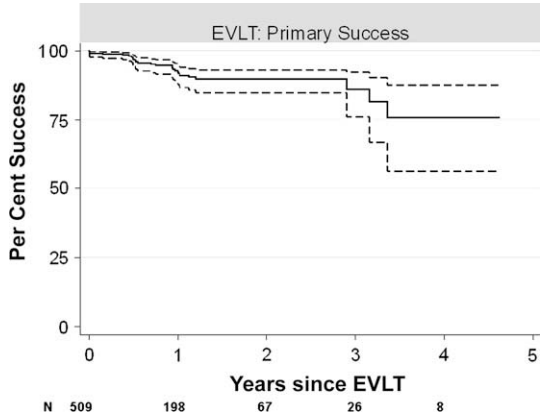

Figure 4 Kaplan—Meier life table analysis of primary success rates after endovenous laser therapy for all veins treated.

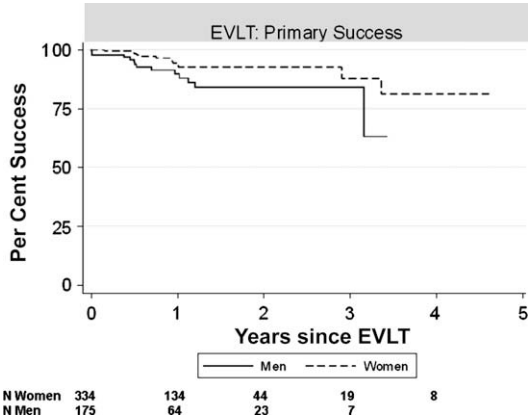

Figure 6 Kaplan—Meier life table analysis of primary success rates after endovenous laser therapy according to sex of the patients.

who might be at a poor risk for surgery. Perivenous anaesthesia allows veins of any diameter or length to be treated by EVLT but it is probably necessary to ensure that large diameter veins are adequately compressed. There is little information about the best protocol for rate of withdrawal of the probe and power applied for any of the laser frequencies used and it is possible that the thermal damage was too low in this study and that late results might have been improved by using more power.

It was not possible from the post-operative scans in this study to determine the mechanism whereby the vein was occluded. The usual early appearance of a non-echoic lumen suggesting thrombosis quickly converted to an echoic lumen suggesting fibrosis with shrinkage leading to a fine white cord. However, this was not evaluated systematically. It has been considered by some that EVLT with the 810 nm probe acts through haemoglobin to damage the vein by forming steam leading to endothelial denudation, collagen contraction and vein wall fibrosis[6—8] although the mechanism for any wavelength is uncertain.[9]

We have previously reported our early experience with EVLT.[10] In the present expanded series, life table analysis showed ultrasound control in 76% at four years. Most were relatively easy successfully to treat with further UGS resulting in secondary success at four years in 97%, with only 5 patients electing not to have further treatment. Min and colleagues showed similar results.[2] Early studies reported satisfactory results for the great[2—4] and small[5] saphenous veins although life table analysis was not used to present results. More recent studies show excellent results for the great and small saphenous veins.[10—12] At least two non-randomized[13,14] and two randomized[15,16] trials comparing EVLT and surgery for great saphenous reflux show early outcome to be at least as good for EVLT as for surgery, including technical success, safety, post-operative pain, quality of life and cost-effectiveness. Early results at 6 months from a randomized Danish study show comparable early success, patient recovery times and time to return to work, and post-operative pain and need for analgesics.[16]

Ultrasound surveillance detects a high incidence of failure after surgery for varicose veins.[1] Van Rij and colleagues detected 25% recurrence after great saphenous surgery and 50% recurrence after small saphenous surgery at three years.[17] A Swedish study 10 years after great saphenous ligation and stripping showed that 86 of 100 limbs had

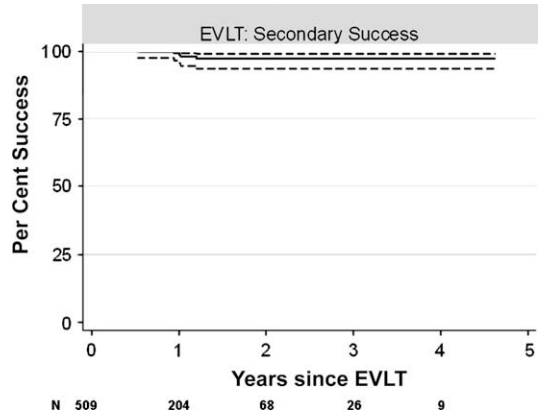

Figure 5 Kaplan—Meier life table analysis of secondary success rates after endovenous laser therapy for all veins treated.

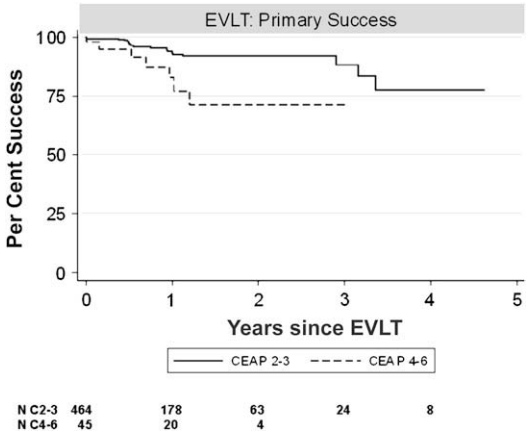

Figure 7 Kaplan—Meier life table analysis of primary success rates after endovenous laser therapy according to clinical CEAP of the limbs.

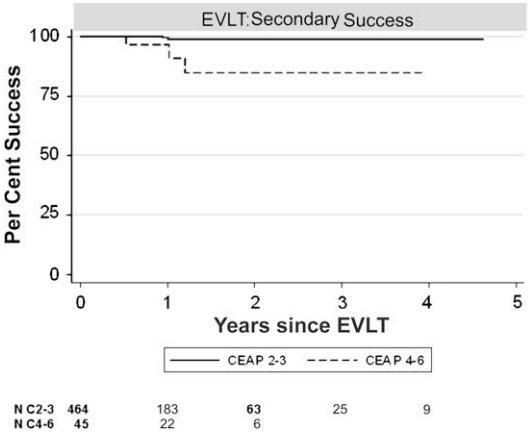

Figure 8 Kaplan–Meier life table analysis of secondary success rates after endovenous laser therapy according to clinical CEAP of the limbs.

recurrence involving segments of the great saphenous veins.[18] There is a high incidence of reconnection from the common femoral vein or low abdominal or pelvic veins to thigh tributaries after surgery.[19,20] Traditional teaching to ligate all tributaries at the saphenofemoral junction may actually predispose to reconnections into thigh veins rather than normal drainage through the saphenous junction. Endovenous techniques are not associated with a high incidence of recurrence in the groin [21,22] suggesting that leaving low abdominal or pelvic tributaries may be an advantage.

Ultrasound after small saphenous surgery demonstrated that only 39% of 59 operations were successful at early follow-up in a British report,[23] and only 5 of 28 operations were successful at 3 months in a Dutch study.[24] A British review suggests that this may be due to reluctance to strip the small saphenous vein because of fear of nerve injury.[25]

An alternative endovenous technique using thermal ablation from a radiofrequency probe (RF) shows good results with low complication rates.[26] Ultrasound surveillance shows occlusion of most saphenous veins and infrequent development of new veins in the groin with this technique.[27] Randomized trials of RF vs surgery found significantly less post-operative pain, faster rehabilitation, lower cost and persisting better quality of life, as well as comparable control of the veins.[28,29] Reports show satisfactory outcome after treatment for saphenous reflux by UGS[30–32] but we have demonstrated worse results for larger diameter saphenous veins.[33]

Thromboembolic complications occur with any treatment for varicose veins and EVLT had a 3% incidence of thromboembolic complications in this series. Van Rij and colleagues documented deep vein thrombosis in 5.3% of limbs after varicose vein surgery although most were localized to tibial veins.[34]

Varicose veins are an extremely common problem in the community. Their treatment places a considerable strain on the medical system with long waiting times for operation in public hospitals. Endovenous procedures allow for more efficient management of large numbers with out-patient treatment. EVLT is simple to perform, well accepted by patients, and relatively atraumatic and safe. This study shows that EVLT is effective for dealing with varicose veins with saphenous reflux. It may well be that success rates will improve with increasing power applied to the veins as suggested by Proebstle.[35] Longer follow up is required to allow confidence of lasting success. Ongoing randomized trials will be required to better assess the value of EVLT compared to surgery.

Table 1 Cox regression analysis for covariates that influenced outcome after endovenous laser therapy

Covariate	Level	Hazard ratio	95% Confidence interval	*P*-value
Primary success				
Sex	Male[a]	1.00		
	Female	0.44	0.19–0.99	0.047
CEAP	C2–3[a]	1.00		
	C4–6	2.25	0.91–5.59	0.080
Age	0–39[a]	1.00		
	40–49	0.43	0.11–1.66	0.218
	50–59	0.46	0.15–1.36	0.160
	60+	1.51	0.53–4.31	0.439
Secondary success				
CEAP	C2–3[a]	1.00		
	C4–6	12.24	2.02–74.1	0.006

[a] Baseline category.

Conflict of Interest

The authors have no conflict of interest.

Acknowledgements

We thank our sonographers and nursing sister, Amy Clough, Christine Bolton, Michelle Rodeh, Jayne Chambers, Penny Koh and Jacqui Kirwan for their invaluable assistance and advice.

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